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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,739	11/16/2000	Hongkui Jin	GENENT.68A2D1	7262

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/715,739	JIN ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,30,32-36,40-48 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,30,32-36,40-48 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. The Amendment dated 4/2/04 has been entered into the record.

B. Claims 29, 30, 32-36, 40-48 and 55 are pending and are the subject of this Office Action.

C. All Statues under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Objections

A. All claim objections have been withdraw in view of Applicants' amendments to, or cancellation of, the claims.

B. Claim 36 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is not clear if the hypertrophy of claim 29 is preexistent. It appears, in light of claim 36, that the patient already suffers from hypertrophy. However, if this is not the case, then claim 36 is not further limiting, since claim 29 encompasses both patients at risk, as well as patients who currently have the condition.

C. Claim 42 is objected to since the syntax could be improved by removing the word "a" before "carvedilol."

3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 29, 30, 31-36, 40-48 and 56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting fluprostenol-induced cardiac hypertrophy in rats, does not reasonably provide enablement for treating or preventing cardiac hypertrophy produced by any and all means, including those recited in claim 56, where the hypertrophy is "other than hypertrophic cardiomyopathy of viral origin." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The breadth of the claims is excessive. Applicants have only provided sufficient guidance and working examples of the ability of IFN-gamma to inhibit fluprostenol-induced cardiomyopathy in rats (Example 2 of the specification). However, the claims read on a method of treating cardiac hypertrophy in a patient wherein the cardiac hypertrophy is caused by a large number of conditions, including that caused by a condition other than that of viral origin. Furthermore, the definition of "treat" encompasses "prevent" as seen on page 11 of the specification. Applicants have not demonstrated that they are able to prevent cardiac hypertrophy in a patient other than for that induced by fluprostenol, nor have they demonstrated that all cardiac hypertrophy occurs via a common mechanism which is able to be remedied by IFN-gamma. Therefore, given this lack of guidance and working examples for the ability to treat the numerous types of cardiac hypertrophy encompassed by the claims, as well as for this lack of guidance on preventing cardiac hypertrophy, it would not be predictable to one of ordinary skill in the art how to treat or prevent hypertrophy by all conditions encompassed by the claims.

In summary, the breadth of the claims is excessive regarding Applicants' claiming a method of treating cardiac hypertrophy caused by all the conditions covered in the claims. There is a lack of guidance and working examples of treating, including preventing, cardiac hypertrophy caused by these

conditions. For these reasons, it is unpredictable to the artisan how to use IFN to treat, including prevent, cardiac hypertrophy induced by these various conditions. Therefore, the Examiner has concluded that undue experimentation is required to practice the invention as claimed.

4. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claim 56 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding claim 56, Applicants have not adequately described the genus of cardiac hypertrophy associated with hypertension which is caused by a condition other than a cardiomyopathy of viral origin.

5. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 29, 30, 31-36, 40-48 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear if the hypertrophy of claim 29 is preexistent. It appears, in light of claim 36, that the patient already suffers from hypertrophy. However, if this is not the case, then claim 36 is not further limiting, since claim 29 encompasses both patients at risk, as well as patients who currently have the condition.

6. Claim Rejections - 35 USC § 102

A. The rejection of claim 36 under 35 USC 102 has been withdrawn in view of the fact that Torigoe et al. do not teach administering patients at risk of developing cardiac hypertrophy.

7. Conclusion

A. The Examiner apologizes for stating that numerous claims were allowable. However, upon further review of the claims and specification, new issues have been identified. Therefore, no claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
June 08, 2004

ROBERT LANDSMAN
PATENT EXAMINER